UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEPOMED, INC., and VALEANT INTERNATIONAL (BARBADOS) SRL, Plaintiffs, v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES LTD., and SUN PHARMACEUTICAL INDUSTRIES INC., Defendants.	Honorable Joel A. Pisano, U.S.D.J. Civil Action No. 11-CV-3553 (JAP) (TJB)

SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES LTD., AND SUN PHARMACEUTICAL INDUSTRIES, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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INTRODUCTION

In its opening brief, Sun relied on the intrinsic record and common sense to support its constructions. Plaintiffs, in contrast, turned to a 70-page, self-serving expert declaration. The Federal Circuit in *Phillips* held that such "conclusory, unsupported assertions by experts . . . are not useful to a court." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (en banc). This case provides a perfect example of why the Federal Circuit was right.

When confronted with the intrinsic record at deposition, Plaintiffs' expert *agreed* with Sun on many of the disputed terms. And, remarkably, he rejected Plaintiffs' interpretation of one claim term—"solid polymeric matrix with drug dispersed therein." When asked about Plaintiffs' purported depiction of that term in their brief (Fig. 1), Plaintiffs' own expert candidly replied: "*I just don't think this has anything to do with what the patent is about*." Ex. 17 (Hopfenberg Dep.) at 140:18-19 (emphasis added).[1]

The same could be said for Plaintiffs' other constructions. For example, Plaintiffs are attempting to argue that Sun's circular tablet infringes the '962 patent, which requires a *non*-circular shape. Sun's position is that the non-circular limitation refers to the *largest* planar projection of the matrix (i.e., the face of the tablet), as opposed to the thickness of the tablet. In response, Plaintiffs repeatedly represented to the Court: "*There is no support in the intrinsic evidence for such a limitation, and Sun does not cite to anything to support the 'largest' limitation*." Pls. Br. 34 (emphasis added); *see also id.* at 36. But this argument is frivolous. As Sun previously brought to Plaintiffs' attention, the specification expressly refers to "the *largest* planar projection of the shape" of the matrix. Ex. 7 ('962 patent) col. 4, ll. 8-15 (emphasis added); Dkt. 43-1 at 55 & 57-58 of 59.

[1] Exhibits 17 through 20 are attached to the May 4, 2012 Declaration of Melissa Steedle Bogad, filed herewith. Exhibits 1 through 16 were filed with Sun's Opening Claim Construction Brief.

These are just two examples of how Plaintiffs are attempting to mislead the Court into adopting constructions necessary to support an infringement claim. Unfortunately for Plaintiffs, the intrinsic record does not support their constructions. As one Federal Circuit judge aptly put it, constructions are not a "nose of wax to be pushed and shoved into a form that pleases and that produces a particular result a court may desire." *Exxon Chem. Patents Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1563 (Fed. Cir. 1995) (Plager, J., concurring). Instead, this Court should be true to the intrinsic record and adopt Sun's constructions.

ARGUMENT

The parties have asked the Court to dispute a relatively large number of claim terms. But Sun has grouped these terms, thus isolating a discrete number of issues for this Court to resolve.

I. Disputed Terms In The '475 and '280 Patents[2]

A. Terms Describing The Polymeric Matrix

The claims and the specifications of the patents clearly require a dosage form with a specific type of polymeric matrix that:

- contains a sufficient amount of a suitable polymer or polymer mix to render the patented invention operable;
- has the drug dispersed throughout the matrix;
- is able to swell due to the ingress of water; and
- allows for unrestricted swelling.

Plaintiffs' expert (Dr. Hopfenberg) conceded in his declaration and at his deposition that the claimed polymeric matrix has these "special" properties. Ex. 18 (Hopfenberg Decl.) ¶¶ 55-60; Ex. 17 at 38:13-25; 123:15-124:13; 127:7-21. Yet, only Sun's constructions account for

[2] Citations for these two patents will refer to the '475 patent unless otherwise specified because the disclosure in the two patents are identical with the exception of a non-substantive addition in the '280 Patent.

them. Plaintiffs' constructions, in contrast, are overbroad and otherwise inconsistent with the intrinsic evidence.

1. "[P]olymeric matrix" ('475 and '280 Patents)

Sun's Proposed Construction	Plaintiffs' Proposed Construction
A polymeric formulation containing a sufficient amount of a suitable polymer or polymer mix to provide extended, controlled release of a drug dispersed throughout the formulation	A surrounding medium comprising polymer

There is no dispute that this "polymeric matrix" can be comprised of a single polymer or polymer mix. Ex. 17 at 112:16-21. Nor is there any dispute that the purpose of this "polymeric matrix" is to help provide extended, controlled release of a drug. *Id.* at 128:22-129:10. To this end, as Plaintiffs' expert conceded, the patents require a "special" type of polymeric matrix to render the claims operable. Ex. 17 at 86:8-87:7; Ex. 18 ¶ 55. In particular, the "polymeric matrix" described in the patents contains the following two limitations captured only by Sun's construction:

First, as the specification makes clear, the claimed polymeric matrix must be made of a *suitable polymer or polymer mix*—e.g., one that will allow the matrix to be water swellable and thus provide extended, controlled release of a drug. Ex. 2, col. 5, l. 66–col. 6, l. 3; col. 7, ll. 54-58. Plaintiffs' expert readily agreed with this limitation. When asked whether "some polymers would be *un*suitable for the systems described in the Patents-In-Suit?" he replied "Certainly." Ex. 17 at 123:18-20 (emphasis added). This concession, alone, confirms that Plaintiffs' construction for "polymeric matrix" is overbroad because it includes polymers "unsuitable" for the inventions. A person of ordinary skill in the art would understand that the "polymeric matrix" at issue in the patents does not capture *any* surrounding medium comprising polymer, as Plaintiffs would have the Court believe. *See id.*

Second, the specification also makes clear that the matrix required by the patents must have a *sufficient amount* of the suitable polymer to render the patented invention operable. Ex. 2 col. 9, ll. 22-41. Again, Plaintiffs' expert agreed with this limitation. When asked whether one would "need enough polymers" to satisfy the drug-to-polymer ratios required by the claims, he responded: "That's my understanding." Ex. 17 at 127:19-21.

Plaintiffs nonetheless criticize Sun's construction as being "front-loaded," arguing that Sun's construction unnecessarily repeats other claim limitations. But Sun's construction does not result in any redundancies. Instead, unlike Plaintiffs' construction, Sun's construction makes it clear that the applicants used the term "polymeric matrix" to mean a "special" type of polymeric formulation necessary to make the patented invention operable—i.e., a polymeric matrix that contains a sufficient amount of a suitable polymer or polymer mix to provide extended, controlled release of a drug dispersed throughout the formulation (see next section for discussion of "throughout"). The other claim limitations are more specific—e.g., requiring that the matrix be water-swellable and satisfy certain drug-to-polymer ratios.

Plaintiffs also misconstrue Sun's construction as suggesting that a "polymeric matrix" itself should be defined to include the drug. But that is *not* what Sun is saying. Instead, its construction requires a sufficient amount of a suitable polymer such that a drug *can be* dispersed throughout the formulation. As a plain reading of the specification makes clear, if the "polymeric matrix" were incapable of having a drug dispersed throughout the formulation (or, to use Plaintiffs' term, "medium"), such matrix would not satisfy the limitations of the claim language—thus rendering the patent claims inoperable. Ex. 2, col. 5, l. 57–col. 6, l. 17; *see also Cordis v. Medtronic*, 511 F.3d 1157, 1174 (Fed. Cir. 2008) ("[A] construction that renders the claimed invention inoperable should be viewed with extreme skepticism."). To avoid any

confusion, however, Sun would be willing to clarify its construction to read: "A polymeric *medium* containing a sufficient amount of a suitable polymer or polymer mix *such that this medium can* provide extended, controlled release of a drug dispersed throughout the formulation."

2. [A] solid polymeric matrix *with drug dispersed therein* ('475 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
A solid polymeric matrix with the drug dispersed throughout the matrix	A medium comprising polymer that surrounds drug particles

One or more polymers forming a solid polymeric matrix *with said drug incorporated therein* ('280 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
The drug is dispersed throughout a solid polymeric matrix formed by one or more polymers; see also the constructions for "polymeric matrix" and "polymeric matrix with drug dispersed therein."	One or more polymeric materials forming a medium that surrounds drug particles; see construction for "polymeric matrix with drug dispersed therein"

Plaintiffs' expert confirmed Sun's position that the terms "dispersed therein" and "incorporated therein" both mean "dispersed throughout." He also flatly *rejected* Plaintiffs' reading of this term.

First, Plaintiffs' expert did not dispute that the plain and ordinary meaning of "disperse"—as defined by a dictionary he himself cited in his declaration—is "[t]o distribute (as fine particles) more or less evenly *throughout a medium*." Ex. 17 at 132:25-133:12; 136:8-17 (emphasis added); *see also* Ex. 18 ¶ 119. This is precisely how the prior art refers to dispersing a drug in a polymeric matrix: "[t]he drug is assumed to be homogeneously dissolved and

distributed *throughout the polymer*" such that "the rate of drug diffusion through the water-swollen polymer is the rate-limiting step." Ex. 3 at 244 (emphasis added).[3]

Second, Plaintiffs' expert depicted this claim term as showing the drug dispersed *throughout* the matrix. As he put it: "When I say 'drug dispersed in a polymeric matrix,' if we believe a picture is worth a thousand words, I'm directed to Figure 2." Ex. 17 at 38:19-23. He further explained that "Figure 4 is really the ultimate picture of what this invention is about." *Id.* at 136:19-21. As shown below, Dr. Hopfenberg's Figures 2 and 4 clearly show a drug dispersed *throughout* the matrix:

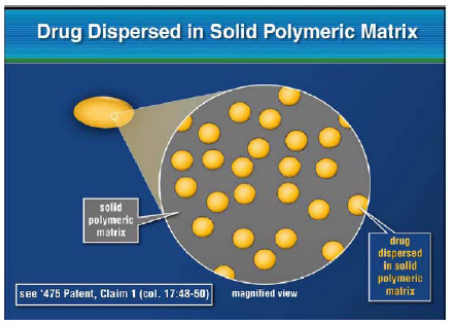


Figure 2

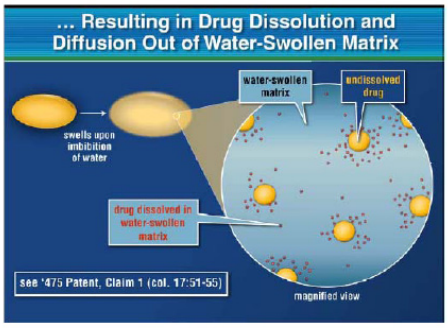


Figure 4

Ex. 18 at 25-26.

Third, Plaintiffs' expert equated the terms "dispersed therein" and "incorporating therein," agreeing that "'incorporated' means the same thing as 'dispersed' in terms of the patent." Ex. 17 at 103:2-15, 103:25-104:8. In other words, both "dispersed therein" and "incorporated therein" mean "dispersed throughout"—consistent with Sun's constructions.

While the evidence above is sufficient to rule in Sun's favor, the Court should take special note of Dr. Hopfenberg's candid testimony that Plaintiffs have mischaracterized their

[3] Plaintiffs' expert disputed that the drug necessarily is *homogenously* distributed throughout the polymer. Ex. 17 at 65:19-66:8. But Sun's construction does not require a homogenous distribution throughout the polymer.

patents. In their brief, Plaintiffs represented to the Court that Sun's construction excludes a "preferred embodiment[]"—i.e., "an embodiment where the drug is localized in the dosage form." Pls. Br. 13. Citing a reference in the specification saying that the polymer is "impregnated" with the drug, Plaintiffs argued that this "impregnated" matrix is "like the yolk of an egg being surrounded by the 'egg white.'" *Id.* at 16. They went so far as to create a graphic (Fig. 1) to illustrate this purported "preferred embodiment":

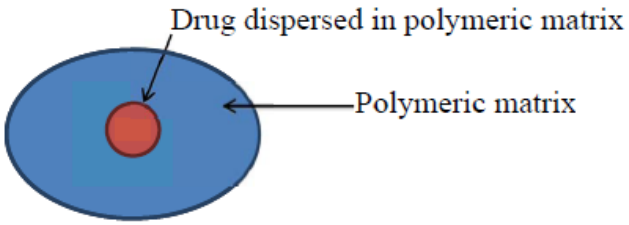


Figure 1. Embodiment of drug "dispersed" in the polymeric matrix

Id. at 14, 16.

But Plaintiffs' own expert testified that he has no "sympathy with the drawing"—i.e., Plaintiffs' Figure 1—because "I just don't think this has anything to do with what the patent is about":

> Q. How would—if you know, how would one go about formulating a drug dispersed in a polymeric matrix according to Figure 1 of Exhibit 8 [Plaintiffs' Opening Claim Construction Brief]?
>
> A. . . . . I would never have proposed this because I think it's ambiguous, and ***one is not enlightened by this.*** The only way I can understand this in the context of the patent at issue is we're looking at a small microcosm of Figure 4 [of his declaration] focusing on a single particle and the – and the matrix that's around it. ***So I just don't think this has anything to do with what the patent is about.*** If you take it literally, it's just a—a small element of that matrix.
>
> ***
>
> Q. So, you would not describe the polymeric matrix in the Patents-in-Suit as like a yolk of an egg being surrounded by the egg white? Is that fair?

> A. The only place I think that does have relevance to the patents is if we were looking at a single particle and where the particle itself would be the yolk and arbitrarily defined amount of polymer around it would be the white. I—I—***I am not in sympathy with the metaphor, nor am I in sympathy with the drawing. I'll say no more.***

Ex. 17 at 140:4-21; 141:6-19 (emphasis added) (objections to form omitted); *see also id.* at 103:2-15; 108:12-20 (explaining that term "impregnated" essentially means "dispersed or incorporated"). Nothing more needs to be said. Plaintiffs have overreached according to their own expert, and their construction should be rejected for this reason alone.

3. Said polymeric matrix being one that *swells upon imbibition of water* thereby attaining a size large enough to promote retention in the stomach during the fed mode ('475 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
Due to the ingress of water into the polymeric matrix, that matrix increases the size of the dosage form such that when it is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours	The surrounding medium comprising polymer increases in size such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours

Putting aside the parties' disagreement with respect to "polymeric matrix," the sole dispute with regard to this term is whether the phrase "due to the ingress of water into the polymeric matrix" should be part of the construction. It should be, as confirmed by the intrinsic record, Plaintiffs' expert, and the claim construction ruling by another court.

First, the phrase "due to the ingress of water" gives meaning to the words "swells upon imbibition of water" in the claim term. In fact, the specification uses this precise phrase when unequivocally describing the swelling of the matrix:

> The hydrophilicity and water swellability of these polymers cause the drug-containing matrices to swell in size in the gastric cavity ***due to ingress of water*** in order to achieve a size that will be retained in the stomach when introduced during the fed mode.

Ex. 2, col. 9, ll. 1-5 (emphasis added).

Second, Plaintiffs' expert, once again, supports Sun's construction. In his declaration, Dr. Hopfenberg described the polymeric matrix of the patents-in-suit as having "a special property of being able to absorb or imbibe water" to become a "water-induced" swollen matrix. Ex. 18 ¶ 55 (p. 25). He further testified that, although he was "giving away the store," he has no objection to Sun's construction: "I think the person of ordinary skill knows I have no objection with the notion that there would be an ingress of water." Ex. 17 at 164:7-8, 20-22.

Third, the court in the *Depomed v. Lupin* case construed this very term as: "[t]he dosage form, which comprises a polymeric matrix, increases in size ***due to the ingress of water***, such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." Pls. Ex. 10 (*Depomed v. Lupin* Claim Construction Order) at 12 (emphasis added). In so ruling, the *Lupin* court noted that "[b]oth parties agree that *because of the ingestion of water*, the polymeric matrix increases to a size that causes the dosage form to remain in the stomach for some period of time." *Id.* at 9 (emphasis added). Plaintiffs fail to explain why they changed positions.

4. Said dosage form being one that when *swollen in a dimensionally unrestricted manner* as a result of imbibition of water is of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said/the fed mode ('280 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
Upon unrestricted swelling, the dosage form reaches a size larger than the diameter of the human pylorus in the fed mode, promoting extended retention of the dosage form in the stomach	The polymeric matrix of the drug dosage form increases in size such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours

The dispute here turns on whether this term requires a dosage form with "unrestricted swelling." There is no denying this plain and ordinary reading of this claim term, which expressly says the "dosage form" is "*swollen in a dimensionally unrestricted manner*."

In their brief, Plaintiffs rely on the previous claim constructions in the related *Ivax* and *Lupin* cases. But the courts in those cases left that phrase with no meaning. Those prior constructions thus carry no weight here. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950-51 (Fed. Cir. 2006) (claim limitations cannot be deemed "merely superfluous").

Finally, to the extent Plaintiffs quibble with the term "unrestricted swelling," arguing that the patent refers to "dimensionally unrestricted swelling," that is a distinction without a difference. Plaintiffs themselves refer to these phrases interchangeably. *See* Pls. Br. 32 ("[T]hroughout the specification are descriptions that the dosage form swells in an unrestricted manner when it is placed in contact with water.") (citing patent at col. 4, ll. 48-53, which says "dimensionally unrestricted manner"); *compare* Ex. 7 at col. 4, ll. 51-52 ("dimensionally unrestricted manner") *with id.* at col. 11, ll. 19-20 (saying just "unrestricted manner"). In fact, Sun would have no objection to construing this term as "Upon *dimensionally* unrestricted swelling, the dosage form reaches a size larger than the diameter of the human pylorus in the fed mode, promoting extended retention of the dosage form in the stomach."

B. Terms Requiring The Water-Swollen Polymeric Matrix To Control Release Of The Drug

With regard to the following two terms, only Sun's construction properly includes "water-swollen" to characterize the polymeric matrix:

Dissolution and diffusion ('475 and '280 Patents)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
Rapid dissolution of the drug, followed by slow diffusion of the drug out of the ***water-swollen*** polymeric matrix, such that the drug is released at a rate controlled by the rate of diffusion from such matrix	Rapid dissolution of the drug by the gastric fluid, followed by slow diffusion of the drug out of the matrix, such that the drug is released at a rate primarily controlled by the rate of diffusion

Releases said drug into gastric fluid by dissolution and diffusion of said drug out of said matrix [by said gastric fluid] ('475 and '280 Patents)

Sun's Proposed Construction	Plaintiffs' Proposed Construction
The ***water-swollen*** polymeric matrix controls the dissolution and diffusion of the drug into gastric fluid. See also the constructions for "polymeric matrix," "gastric fluid" and "dissolution and diffusion."	See constructions for "polymeric matrix", "gastric fluid" and "dissolution and diffusion"; all other terms are the plain and ordinary meaning

In fact, Sun's point should not be controversial. First, the intrinsic evidence unambiguously says that the polymeric matrix must be water-swollen to release the drug.

- The specification repeatedly states that the polymeric matrix be "*water-swellable* rather than merely hydrophilic, that has an erosion rate that is substantially slower than its swelling rate, and that *releases the drug primarily by diffusion*." Ex. 2, col. 5, ll. 57-62 (emphasis added).

- The claims themselves refer to a dosage form or polymeric matrix that "swells upon imbibition of water," Ex. 2, claim 1, and becomes "swollen in a dimensionally unrestricted manner as a result of imbibition of water." Ex. 5, claim 1; *see also* Exs. 2 & 5, claims 34 (same, substituting gastric fluid for water).

Second, Plaintiffs' expert explained in his declaration that the imbibition of water into the claimed polymeric matrix "produces a *swollen dosage form* that (a) causes the dissolution and diffusion of the drug out of the matrix and (b) attains a size that retards the diffusional release of drug from the dosage form into the surrounding aqueous environment." Ex. 18 ¶ 55 (emphasis added). At deposition, Plaintiffs' expert confirmed that Sun's construction is accurate:

> Q. Okay. And do you see in Sun's proposed construction [for "dissolution and diffusion"], it reads: "Rapid dissolution of the drug, followed by slow diffusion of the drug out of the *water-swollen polymeric matrix*"? Do you see that?
>
> A. I do.
>
> Q. Do you agree that that's an accurate description of dissolution and diffusion?
>
> MR. ANDRE: Objection to the form of the question.
>
> A. *Yes, that's accurate*.

Ex. 17 at 171:20-172:6 (emphasis added).

Plaintiffs' expert also failed to support Plaintiffs' position that "Nothing in the specification requires that the polymeric matrix be water-swollen first to effectuate dissolution and diffusion." Pls. Br. 23. In his report, Dr. Hopfenberg said the precise opposite: "water will enter the dosage form to cause matrix swelling and dissolution of the dispersed drug *followed by* diffusion of the drug out of the water-swollen matrix." Ex. 18 ¶ 77 (emphasis added); *see also* Ex. 17 at 76:15-77:15 (same).

Third, even the extrinsic evidence says that a controlled release polymeric matrix releases the drug "through the *water-swollen polymer*." Ex. 3 at 244 (emphasis added).[4]

C. Terms Addressing "All" And "Substantially All"

For the following terms, only Sun's constructions capture the plain and ordinary meaning of "all" (i.e., 100%) and "substantially all" (i.e., about 100%):

Until all of said drug is released ('475 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
Until all of the drug has been released into the gastric fluid	Until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached

Until substantially all of said drug is released ('280 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
Until about 100% of the drug has been released into gastric fluid	At least 80% of the drug has been released after eight hours of immersion in gastric fluid

[4] Plaintiffs cite the constructions by the *Ivax* and *Lupin* courts. But in both cases, the parties did not have a dispute on this issue. In fact, the *Lupin* court noted that "[t]he patent specification states that controlled release of water-soluble drugs can be achieved using a polymeric matrix that swells to create a diffusion barrier so that water soluble drugs are released primarily by diffusion[.]" Pls. Ex. 10 at 13.

Releases substantially all of said drug [within about eight hours] after such immersion ('475 and '280 Patents)

Sun's Proposed Construction	Plaintiffs' Proposed Construction
About 100% of the drug has been released into gastric fluid	At least 80% of the drug has been released after eight hours of immersion in gastric fluid

While releasing substantially all of said drug within the stomach where said drug is maintained in an acidic environment ('475 Patent)

Sun's Proposed Construction	Plaintiffs' Proposed Construction
Releasing about 100% of the drug in the stomach having a pH value of less than 7	At least 80% of the drug has been released after eight hours of immersion in gastric fluid

Plaintiffs do not dispute that the plain and ordinary meaning of "all" and "substantially all" are "100%" and "about 100%," respectively. Instead, they rely solely on extrinsic evidence—i.e., two FDA Guidances for Industry—to contend that "all" and "substantially all" mean a value considerably less than 100%, even as low as 80%. But the '475 and '280 patents do not cite or refer to any FDA documents.

In fact, the notion that the applicants *implicitly* were referring the reader to these FDA Guidances is a fantasy. Both Guidances were not published until September 1997—*after* the applicants filed their June 6, 1997, priority application for the '475 and '280 patents. [redacted] The applicants thus could not have had the FDA Guidances in mind when using the terms "all" and "substantially all." Plaintiffs simply made this up.

In fact, as explained in Sun's Opening Brief, there is nothing in the patents suggesting anything other than that the plain and ordinary meaning of "all" and "substantially all" should apply. On the contrary, the intrinsic record draws a distinction between "substantially all of said drug" and "all of said drug," thus confirming that "all" means what it says and nothing less. *See*

Ex. 2, claim 1; *see also id.* claim 34; *id.* col. 9, ll. 32-36. Also, Figure 4 of the patent shows that 100% of the drug (metformin) is released after eight hours regardless of the type of polymeric matrix used in the formulation. *Id.* Fig. 4.

Consequently, the Court should not turn to extrinsic evidence to vary the ordinary meanings of "all" and "substantially all." *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003) ("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."); *see also Advanced Fiber Tech. (AFT) Trust v. J&L Fiber Servs., Inc.*, -- F.3d --, 2012 WL 1088698, at *7 (Fed. Cir. Apr. 3, 2012) (reversing because district court "reli[ed] on extrinsic evidence that contradicted the patent's specification.").

D. Terms Addressing The Required Drug-To-Polymer Ratios

There does not appear to be any dispute between the parties for the following terms:

A solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 15:85 to about 80:20 ('475 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
A polymeric matrix at a drug to polymer weight ratio from 14.4:85.6 to 80.8:19.2	A medium comprising polymer that surrounds drug particles at a drug to polymer weight ratio from 14.4:85.6 to 80.8:19.2

At a weight ratio of drug to polymer of from 15:85 to 80:20 ('280 Patent)

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
The weight of the drug is 15 to 80% relative to the total weight of drug and polymer in the solid polymeric matrix	Plain and ordinary meaning

At a weight ratio of drug to polymer of from 0.01:99.99 to 80:20 ('280 Patent)

Sun's Proposed Construction	Plaintiffs' Proposed Construction
The weight of the drug is .01% to 80% relative to the total weight of drug and polymer in the solid polymeric matrix	Plain and ordinary meaning

Plaintiffs' expert conceded that Sun's constructions are correct. Ex. 17 at 158:19-159:21; 160:1-23. And Plaintiffs have never offered any different constructions. Yet, they have not agreed to Sun's request that the parties deem these terms undisputed. Ex. 20 (4/26/12 Ltr. from John K. Hsu to Lisa Kobialka and email response from Lisa Kobialka). To be sure, Plaintiffs are inexplicably wasting the Court's time by continuing to dispute these terms.[5]

II. Disputed Terms In The '667 Patent

A. Terms Relating To First Solid Polymeric Matrix

The parties have construed the two terms below in a manner consistent with similar terms ("polymeric matrix" and "solid polymeric matrix with drug dispersed therein") used in the '475 and '280 patents:

First solid polymeric matrix

Sun's Proposed Construction	Plaintiffs' Proposed Construction
A solid polymeric formulation containing a sufficient amount of a suitable polymer or polymer mix to provide extended, controlled release of a drug dispersed throughout the formulation	Plain and ordinary meaning

[5] In agreeing that Sun's construction is the plain and ordinary meaning, Dr. Hopfenberg also testified that the word "polymer" in these terms really means "polymeric matrix with all of the components included thereto." Ex. 17, 160:8-17. But Plaintiffs never offered a special construction for the term "polymer." And this after-the-fact testimony is contrary to Plaintiffs' construction of "[a] solid *polymeric matrix* with said drug dispersed therein at a weight ratio of drug to *polymer* of from about 15:85 to about 80:20," which draws a distinction between "polymeric matrix" and "polymer." *See Phillips*, 415 F.3d at 1318 (rejecting usefulness of "conclusory, unsupported assertions by experts" in claim construction).

A core comprising a first solid polymeric matrix with said drug dispersed therein

Sun's Proposed Construction	Plaintiffs' Proposed Construction
The core of a drug dosage form comprising a drug dispersed throughout a first solid polymeric matrix	A core comprising a first medium comprising polymeric materials that surrounds drug particles

As Plaintiffs' expert explained: "I think the polymeric matrix, per se, is similar in both" patents. Ex. 17 at 242:10-22. Sun agrees. Thus, it incorporates by reference its arguments relating to "polymeric matrix" above and in its opening claim construction brief.

B. A second solid polymeric matrix that swells upon imbibition of water to a size large enough to promote retention in the stomach while the stomach is in fed mode

Sun's Proposed Construction	Plaintiffs' Proposed Construction
A second solid polymeric formulation comprised of a water-swellable polymer that surrounds and fully encases the core, is of sufficient thickness and strength that it is not disrupted by the swelling, and remains intact and of a size large enough to promote gastric retention; the "shell"	A second medium comprising polymeric materials which increase in size such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours

Only Sun's construction sufficiently captures the following four limitations of this claim. First, Plaintiffs' construction ignores "swells upon imbibition of water," which Plaintiffs' expert agrees must occur:

> Q. Okay. You agree that the shell swells when it's placed in gastric fluid, though; right?
>
> A. Yes.

Id. at 246:22-24.

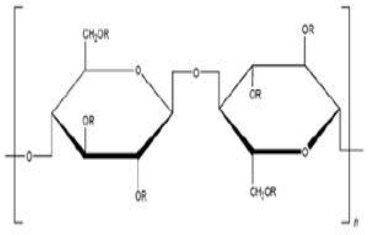
Second, this water-swellable polymer must *surround and fully encase the core*. Claim 1 itself describes "a shell encasing said core." Ex. 6, col. 21, l. 42. Sun's construction tracks the language of the specification, which explains that the shell is comprised of a second "matrix

forming a casing *that surrounds and fully encases the core*, the casing being of polymeric material that swells upon imbibition of water[.]" *Id.* col. 7, ll. 11-13 (emphasis added). Plaintiffs, in contrast, ignore this limitation, which defines how the "second solid polymeric matrix" is incorporated into the formulation.

Third, as the specification again makes clear, this second solid polymeric formulation must be "*of sufficient thickness and strength that it is not disrupted by the swelling and remains intact* during substantially the entire period of drug release." *Id.* col. 7, ll. 17-20 (emphasis added). Put simply, the shell in the claimed invention cannot dissolve or erode before substantially all the drug is released.

Fourth, this shell must be capable of swelling, while remaining intact, *to a size large enough to promote gastric retention*. This limitation, too, comes directly from the language of this claim term, which expressly requires "a second solid polymeric matrix that swells upon imbibition of water to a size large enough to promote retention in the stomach while the stomach is in a fed mode." *Id.* col. 21, ll. 42-45; *see also id.* col. 7, ll. 12-14; *see also id.*, Abstract.

C. Hydroxyalkyl-substituted cellulose

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
A cellulose derivative having the structure  which dissolves in the GI tract in a predictably delayed manner wherein at least one R has a free hydroxyl group and is represented by $-(AO)_mH$ wherein A is a straight chain or branched alkyl	Plain and ordinary meaning

Plaintiffs construe the term as "plain and ordinary meaning," but they do not give any further explanation. At his deposition, Plaintiffs' expert testified that Sun's definition is "close but no cigar" because the "R" in Sun's definition is not properly defined. Ex. 17 at 256:20-23, 258:5-6. Still, neither Dr. Hopfenberg nor Plaintiffs actually offer a construction for this term. In contrast, Sun has set forth a construction and has supported it by extrinsic evidence. *See* Ex. 13 at 3. Moreover, in response to Dr. Hopfenberg's testimony, Sun's expert, Dr. Umesh Banakar, explains that a person of ordinary skill in the art would understand Sun's construction as properly covering a hydroxyalkyl-substituted cellulose. Banakar Decl. ¶¶ 23-25.

III. Disputed Terms In The '962 Patent

A. Terms Requiring A Matrix Capable Of Swelling In An Unrestricted Manner

When read in the context of claim 1 as a whole, both terms below emphasize that the dosage form cannot contain any component that restricts (or hinders) the polymeric matrix from freely swelling:

Dosage form *consisting essentially of* a solid monolithic matrix with said drug contained therein

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
Dosage form with a solid monolithic matrix containing the drug and no other components that restrict swelling of the matrix	See constructions for "solid monolithic matrix" and "drug contained therein."

Swells in an *unrestricted manner* along both such axes

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
No component of the dosage form hinders swelling of the matrix in any dimension (i.e., prevents completely or partially the matrix from swelling)	Imbibition of fluid causes an increase in volume of the matrix, wherein the relative length of both axes after imbibitions of fluid is substantially the same as the relative dimensions of the original matrix

As Sun explained in its opening brief, and as the applicants repeatedly emphasized, the matrix cannot contain any component that restricts swelling of the matrix in any dimension. The specification requires the matrix to be "swellable" and that such swelling be "*dimensionally unrestricted*." Ex. 7, col. 3, ll. 52-53 & col. 4, ll. 48-52 (emphasis added). Even the prosecution history relied on by Plaintiffs supports Sun's construction. There, the applicants represented that "the concept of constrained swelling . . . is diametrically opposed to *the concept of dimensionally unrestricted swelling which is the basis for the creation of the Applicants' invention*." Pls. Br. 33 (emphasis added). Simple logic dictates that the matrix cannot be "dimensionally unrestricted" if it contains components that restrict swelling of the matrix. Equally important, only Sun's construction gives meaning to the phrase "consisting essentially of," which is intended to modify claim language requiring the "matrix" to "be[] one that *swells in an unrestricted manner* along both [orthogonal] axes upon imbibition of water[.]" Ex. 7, col. 11, ll. 19-20 (emphasis added).

Plaintiffs nonetheless offer three arguments to support their constructions, each of which is plainly wrong, or otherwise misplaced:

First, Plaintiffs argue that the phrase "and no other components that restrict swelling" in Sun's construction of the first term is "redundant." Pls. Br. 32. In reality, however, Plaintiffs are trying to ignore the claim language "consisting essentially of," which they cannot do. *See Becton Dickinson and Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1257 (Fed. Cir. 2010) (patent claims must be "interpreted with an eye toward giving effect to all terms in the claim"). "Consisting essentially of" is a common patent phase construed by the Federal Circuit to preclude unlisted ingredients that "materially affect the basic and novel properties of the patented invention." *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). To be sure, adding a component that restricts swelling of the matrix would materially affect the basic

and novel properties of the invention covered by claim 1, which expressly requires a matrix that "swells in an unrestricted manner along both . . . axes." Ex. 7, col. 11, ll. 19-20.

In fact, the applicants highlighted the importance of this phrase to patentability by filing a Certificate of Correction that changed "said dosage form *comprising* a solid monolithic matrix" to "said dosage form *consisting essentially of* a solid monolithic matrix." *Id*., last page (emphasis added). This change was necessary to distinguish prior art (the Wong reference) where the dosage form included a component (a band) that *did* restrict swelling of the matrix. The applicants represented to the Patent Office that, unlike in the prior art Wong reference, their "solid monolithic matrix [must] *swell in an unrestricted manner*." Ex. 14 at 10 (emphasis added); *see also id.* ("Applicants . . . recite a solid monolithic matrix swelling in an unrestricted manner along both axes."). Again, the only way the matrix can "swell in an unrestricted manner" is if it contains no components that restrict such swelling in any dimension. *See, e.g.*, *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretations of claim terms so as to exclude any interpretation that was disclaimed during prosecution.").[6]

Second, Plaintiffs have improperly read "swells in an unrestricted manner along both such axes" as requiring the swelling of the matrix to be "substantially the same" along both axes. In support, they cite col. 4, lines 7-48 of the specification. Pls. Br. 32. But this section in no way supports their construction that "the relative length of both axes after imbibitions of fluid [be] substantially the same as the relative dimensions of the original matrix." Plaintiffs pulled this

[6] To address fully Plaintiffs' contention of redundancy, if (but only if) the Court were to accept Sun's construction of "swells in an unrestricted manner along both such axes," Sun would agree with Plaintiffs that the term "dosage form consisting essentially of a solid monolithic matrix with said drug contained therein" subsumes the definition of "solid monolithic matrix" and there is no need to construe the remaining claim language.

construction from thin air. The intrinsic record simply focuses on a matrix that is dimensionally unrestricted, a term that necessarily precludes components that restrict swelling of the matrix.

Third, Plaintiffs argue that Sun's construction excludes a preferred embodiment. Once again, however, they have distorted the specification and prosecution history. Plaintiffs point to specification language saying that "the *dosage form* is a multilayered tablet in which one or more of the layers swells while others do not." Pls. Br. 33 (emphasis added). But this does not mean that, according to claim 1, the *matrix* can contain a component that restricts swelling. Such a reading would contradict the claim language and the prosecution history.

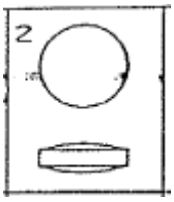
To the extent the claims can even cover a multilayered tablet (an issue not before the Court), such a tablet would have to consist of a *dosage form* containing a separate, non-swellable layer that is surrounded by the matrix. The non-swellable layer cannot restrict swelling of the matrix. If it did, such a formulation would "materially affect the basic and novel properties of the patented invention," *PPG Indus.*, 156 F.3d at 1354, which expressly requires the dosage form to consist essentially of a drug-infused matrix and "swell[] in an unrestricted manner along both . . . axes." Ex. 7, col. 11, ll. 19-20. Plaintiffs' argument thus proves Sun's point—the *matrix* (as opposed to the dosage form) cannot contain any component that restricts (or hinders) swelling.

Additionally, even on its face, Plaintiffs' construction of "Dosage form consisting essentially of a solid monolithic matrix with said drug contained therein" makes no sense because it includes a reference to "drug contained therein." The parties have *not* asked the Court to construe that term.

B. Terms Addressing The Non-Circular Shape Of The Matrix

There is no dispute that all claims in the '962 patent require the matrix to be "non-circular in shape." *Id.* col. 11, l. 14-col. 12, l. 64. Instead, the parties dispute whether the applicants were referring to the shape of the face of the tablet (Sun's position), or the thickness of the tablet

(Plaintiffs' position). To concoct an infringement claim, Plaintiffs are improperly trying to convince the Court that the circular tablet depicted below (plainly excluded from the scope of the patent) is really non-circular in shape. Ex. 17 at 212:10-215:14; 219:3-220:24.



The following terms are related, and can be covered in one discussion:

Said matrix being non-circular in shape and having first and second orthogonal axes of unequal length

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
The largest planar projection of the shape has first and second orthogonal axes of unequal length	Plain and ordinary meaning

Said matrix has a shape which when projected onto a plane

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
The largest planar projection of the tablet	Plain and ordinary meaning

Sun explained in its opening brief that its constructions are not only the plain and ordinary meanings of these terms, they also come *directly from the specification of the '962 patent*. In fact, the applicants repeatedly emphasized the importance of having a non-circular matrix. And they clearly explained that this limitation refers to the shape of the *largest*, two-dimensional planar projection of the matrix:

- The applicants explained that the matrix, "*when projected onto a planar surface*, has two orthogonal axes of different lengths" and thus is "non-circular." Ex. 7, col. 3, ll. 28-31 (emphasis added).

- The applicants confirmed in their detailed description of the invention that they are referring to the *largest* planar projection of the shape of the claimed dosage form, thus excluding a tablet with a round or circular face: "Some of the possible shapes [for the dosage forms of the patented invention] are oval, triangle, almond, peanut,

'bow tie,' parallelogram, trapezoidal, pentagonal, and hexagonal, *provided (as stated above) that the largest planar projection of the shape has at least orthogonal dimensions, one being larger than the other.*" *Id.* col. 4, ll. 8-15 (emphasis added).

- The applicants then distinguished this largest "planar projection" of the shape of the tablet—again, plainly referring to the face of the tablet—from the thickness of the tablet: "One example of a tablet that meets these descriptions [of shape limitations] is a diamond-shaped tablet (i.e., *a tablet whose planar projection is a parallelogram with one diagonal dimension shorter than the other*) in which the shorter diagonal is 0.9 cm and the longer diagonal is 1.5 cm. In this example, *both of these dimensions are substantially greater than the thickness of the tablet*." *Id.* col. 4, ll. 42-48 (emphasis added).

When the applicants referred to the shape of the matrix, therefore, they plainly meant the shape of the *largest* planar projection of the matrix (i.e., the face of the tablet) and not its thickness. As Sun's expert confirms, this is consistent with how a person of ordinary skill in the art would understand the claim elements. Such a person would not read "non-circular in shape" to refer to the thickness of the tablet. Banakar Decl. ¶¶ 17-22.

Curiously, Plaintiffs argue that Sun's construction "is problematic because it attempts to incorporate the limitation 'largest' into its construction." Pls. Br. 34. This position is based entirely on the following misrepresentation: "*There is no support in the intrinsic evidence for such a limitation, and Sun does not cite to anything to support the 'largest' limitation.*" *Id.*; *see also id.* at 36. Both statements are untrue.

As explained above and in Sun's opening brief, the specification expressly emphasizes "that *the largest planar projection of the shape*" of the claimed dosage form must have "*at least two orthogonal dimensions, one being larger than the other.*" Ex. 7, col. 4, ll. 8-15 (emphasis added). As the applicants explained, this particular "non-circular" shape of the *largest planar projection* of the tablet is what allows the claimed dosage form to "enhanc[e] gastric retention" of the drug and also "render the tablets . . . convenient to swallow." *Id.* col. 3, ll. 36-38. Moreover, Sun *did cite* this portion of the specification in the joint claim construction and

prehearing statement. Dkt. 43-1 at pp. 55, 57-58 of 59 (pp. 47, 49-50 of document). Plaintiffs' *sole* objection to Sun's construction thus is frivolous.

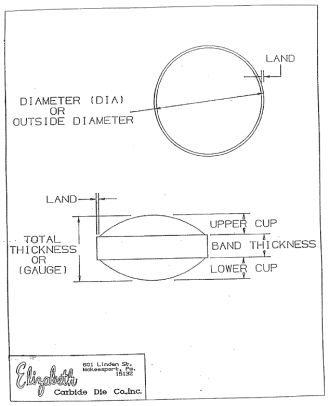
Finally, Plaintiffs have failed to provide any alternative construction and thus have waived their right to do so.

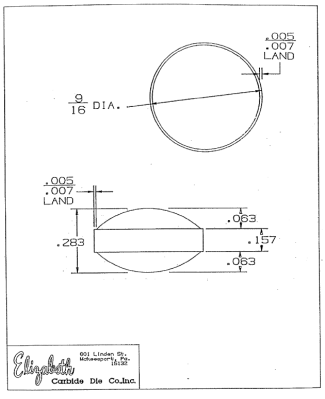
C. An oval

Sun's Proposed Construction	**Plaintiffs' Proposed Construction**
A shape that has a curve that is closed and concave towards the center and has an overall non-circular shape from all dimensions	Any curve that is closed and concave towards the center wherein the geometric form bounded by the closed curve has first and second orthogonal axes of unequal length

There should be no real dispute about what an oval looks like. In fact, both parties have relied on the same extrinsic evidence, a tablet design training manual for Elizabeth Companies. Ex. 15; Pls. Ex. 34. Instead, the dispute here really turns on whether a person of ordinary skill in the art would understand there to be a distinction between a circular and an "oval" tablet. He or she most certainly would.

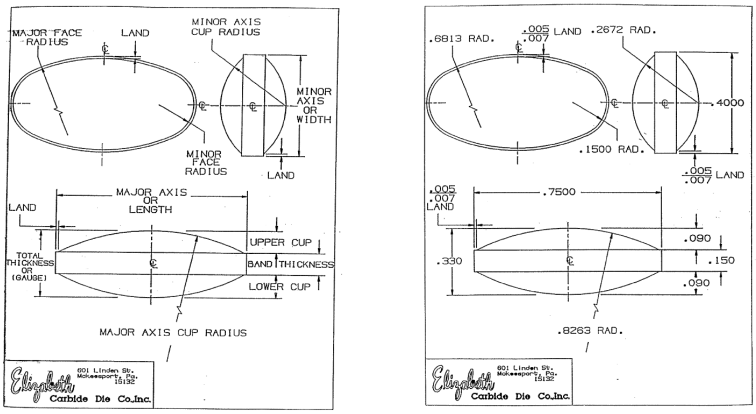
The Elizabeth Companies' training manual draws this very distinction and fully supports Sun's constructions relating to the non-circular shape of the matrix required by the '962 patent. The manual describes a tablet as circular (or "round") if the diameter of the *largest* planar projection of the tablet has first and second orthogonal axes of *equal length*:



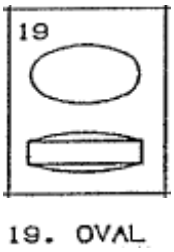


Pls. Ex. 34 at 4, 7-8. A circular tablet may or may not be spherical, and it also may have various degrees of thickness. *See id.* at 15 (pictures 1-16).

The manual draws a stark distinction between a tablet that is circular and one that is oval. *See id.* at 4, 7-10 (distinguishing between "round tablet" nomenclature and dimensioning and an "oval" tablet nomenclature and dimensioning). This distinction turns on the shape of the largest planar projection of the tablet (i.e., its face), *not* its "thickness." For example, the following pages of the document depict an oval-shaped tablet based on its "major face radius":



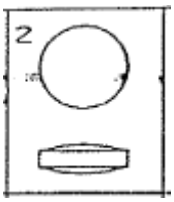
Id. at 9. Page 15 of the document also contains a simple picture of an oval, reproduced below, where the largest planar projection of the tablet is an oval.



Id. at 15.

The Court might think the distinction between a circular and oval-shaped tablet is obvious. But Plaintiffs' expert, Dr. Hopfenberg, has offered an opinion that the following

picture—which Elizabeth Companies refers to as a "round tablet," *id.* at 4, 7-8—actually depicts a *non*-circular (i.e., oval) dosage form:



Id. at 15; Ex. 17 at 219:6-222:10. He purports to justify this opinion by relying on the fact that the thickness of this admittedly *round* tablet is non-circular (in fact, it resembles the thickness of the "oval" tablet depicted above). Ex. 17 at 220:25-222:10. To support his illusion that a round tablet really has an oval shape, Dr. Hopfenberg opines that, at least according to the patent, a tablet *must* be considered "non-circular" unless it is spherical. *Id.* at 226:19-228:8.

But this opinion carries no weight because it conflicts directly with the plain language of the specification. *See AFT Trust*, 2012 WL at *5 ("[C]laims must be read in view of the specification, of which they are a part. . . . [I]f the specification or prosecution history defines a claim term, that definition shall apply even if it differs from the term's ordinary meaning."); *Phillips*, 415 F.3d at 1312, 1315-17 (reaffirming "basic principle" that the specification is "the single best guide to the meaning of a disputed term," "usually dispositive," and "always highly relevant" (internal quotations omitted)). As the applicants made clear: "The shape that achieves this result [enhancing gastric retention] is a *non-circular and non-spherical shape* . . . ." Ex. 7, col. 3, ll. 28-29, 35-36 (emphasis added). To fall within the scope of this patent, therefore, the tablet must be *both* non-circular (referring to the two-dimensional shape of the largest planar projection of the tablet) *and* non-spherical (referring to the three-dimensional shape of the

tablet). Under no stretch of the imagination can a circular (or round) tablet satisfy the limitations of claim 1 of the '962 patent.

Consistent with this clear distinction, Sun is willing to accept Plaintiffs' construction of oval only if the Court were to adopt Sun's constructions of "said matrix being non-circular in shape and having first and second orthogonal axes of unequal length" or "said matrix has a shape which when projected onto a plane." In that situation, claim 1 would require the largest planar projection of the tablet to have a two-dimensional shape that is non-circular, e.g., an oval. If, however, the Court were to consider the meaning of "oval" in a three-dimensional context, it is clear from the specification that the applicants were referring to a tablet with an overall non-circular shape from all dimensions—i.e., a "non-circular *and* non-spherical shape[.]" *Id.* col. 3, ll. 28-31, 36 (emphasis added); *id.* col. 4, ll. 8-16. Plaintiffs' argument to the contrary is gamesmanship that ignores the plain language of the claim and specification.

IV. Disputed Term In The '987 Patent: Curing The Coated Oral Dosage Form At A Temperature Of At Least 55° C

Sun's Proposed Construction	Plaintiffs' Proposed Construction
The coated oral dosage form is raised to a temperature of at least 55° C for curing	Plain and ordinary meaning

The deposition of Plaintiffs' expert has revealed why Plaintiffs refuse to offer a construction for this term. They apparently hope to circumvent claim construction under the guise of "plain and ordinary meaning" expert testimony that mischaracterizes the patent. Specifically, their expert opines that this claim limitation is met as long as the oven used for curing is set at a temperature of at least 55° C—regardless of whether the oral dosage form, itself, reaches the temperature shown on a dial or a meter. *See* Ex. 17 at 231:3-232:3. This is backwards and contrary to the specification.

The applicants repeatedly emphasized in the specification that the dosage form *itself* must reach a temperature of at least 55º Celsius.

First, the patent plainly requires "a polyglycol having a melting point greater than 55° C." Ex. 8 at Abstract; *see also id.* at col. 25, ll. 13-16 (claim 1); *id.* at col. 4, ll. 29-30 (requiring "a poly glycol having a melting point greater than 55° C"); *id.* at col. 4, ll. 42-43 (same); *id.* at col. 9, ll. 10-11 ("The coat formulation also comprises a poly gycol [sic] with a melting point of greater than 55° C.").

Second, the applicants repeatedly required the oral dosage form *itself* to be raised to a temperature equal to or greater than this 55° C melting point. *See id.* at col. 4, ll. 32-34 (requiring "said oral pharmaceutical dosage forms [to be] *cured at a temperature at least equal to or greater than the melting point of the poly glycol*") (emphasis added); *id.* at col. 4, ll. 45-47 (same); *id.* at col. 5, ll. 35-37 (same); *id.* at col. 10, ll. 46-49 ("The coated tablet cores are placed onto a tray and cured . . . in an electrical or steam oven at a temperature above the temperature of the melting point of the polyethylene glycol or derivative thereof."); *see also id.* at col. 10, ll. 60-65 (requires "curing the coated tablets at above the melting temperature of the polyethylene glycol"); *id.* at col. 13, ll. 21-23 (discussing curing "in an oven at 62±2° C" and noting that "[t]his temperature is above the melting temperature of the polyethylene glycol").

Third, the applicants explained that heating the oral dosage form above the 55° C melting point for polyethylene glycol is critical to the patented invention. As they put it: "Surprisingly, . . . applicants have found that addition of polyethylene glycol or its derivatives in the amounts described herein *and curing the coated tablets at above the melting temperature of the polyethylene glycol* provided for a controlled release of the therapeutically active agent." *Id.* at col. 10, ll. 60-65 (emphasis added). As Sun's expert explained, a person of ordinary skill in the

art would understand that when the poly glycol polymer melts during the curing process, it is allowed to form a film that affects the release profile of the drug. Banakar Decl. ¶¶ 27-28. Thus, allowing the polymer to reach its melting point is not a mere after-thought but, instead, materially affects the ability of the formulation to release the drug in a controlled manner. *See id.*

The arguments offered by Plaintiffs and their expert are nonsense and have no support in the intrinsic evidence. Plaintiffs' expert takes the far-fetched position that the temperature of the oral dosage form is irrelevant. When pointed to the fact that the applicants repeatedly instructed the reader to heat the polyglycol above its melting point, he responded by saying this was "*coincidental*." Ex. 17 at 234:18-236:9 (emphasis added). The Court should discard such testimony because it is "conclusory" and "clearly at odds with . . . the written record of the patent." *Phillips*, 415 F.3d at 1318. Plaintiffs even quibble that Sun states that the dosage form is "raised" to at least 55º Celsius. Pls. Br. 40. But any person of ordinary skill in the art would understand that the oral dosage form is cured by raising the temperature.

In sum, the plain and ordinary reading of this claim term is "the coated oral dosage form is raised to a temperature of at least 55° C for curing." As a matter of common sense, if the coated oral dosage form is not raised to this temperature, it cannot possibly be "at least equal to or greater than the melting point of the poly glycol." *See, e.g.*, Ex. 8, col. 4, ll. 32-34.

CONCLUSION

For the reasons set forth above, Sun asks the Court to adopt its constructions of the disputed claim terms.

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CERTIFICATION OF SERVICE

I hereby certify that on May 4, 2012, copies of the foregoing Responsive Claim Construction Brief and supporting documents were served by electronic filing and electronic mail upon all counsel of record.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

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Date: May 4, 2012